



Attorney Docket No.: 38530-0100

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:  
Sarah Anne Robertson *et al.*

Confirmation No.: 2475

Application No.: 09/380,327

Art Unit: 1644

Filed: September 3, 1999

Examiner: Michail A. Belyavskyi

For: **TREATMENT AND DIAGNOSIS OF INFERTILITY USING TGF $\beta$  OR ACTIVIN**

## DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Dr. Carolyn B. Coulam, M.D. being duly warned, hereby declare and say:

1. I am Director of Recurrent Pregnancy Loss and Research at the Rinehart Center for Reproductive Medicine, and Director of the Millenova Immunology Laboratories, Chicago, IL.

2. I have M.D. and M.S. (Biochemistry) degrees from the University of Utah College of Medicine.

3. I am a past President of the American Society for Reproductive Immunology. In 1998 I was awarded the Blackwell Munskgaard Award by the American Society for Reproductive Immunology. This award is presented annually to a senior investigator who has made outstanding contributions to the area of reproductive immunology.

4. I am the principal author of numerous articles related to human infertility and assisted reproduction. My *curriculum vitae* is attached.

5. I am being compensated for preparing this declaration at my normal consulting rate.

6. I have reviewed the following documents:

the disclosure of U.S. Application Serial No. 09/380,327 ("the '327 application");

the Official Actions from the United States Patent Office dated October 6, 2004, March 24, 2005, and August 1, 2005;

U.S. Patent 5,395,825 (1995) - Feinberg *et al.*;

Lea *et al.* AJRI, 34:52-64 (1995);

Prakash, Reprod. Immunol., 35: 403-412 (1981);

Chapter 2: WHO Laboratory Manual for the Examination of Human Semen and Semen-Cervical Mucus Interaction (1987);

Harlow and Lane: A Laboratory Manual, page 61 (1988);

Martin-Villa *et al.*, Bio. Reprod., 55: 620-629 (1996);

Thaler, C., AJRI, 21: 147-150 (1989);

Grainger *et al.* Nature Med., 1,9: 932-937;

Thomas & McLean, AJRI, 6:185-189 (1984);

Nocera & Chu AJRI, 33: 282-291 (1995);

Heidenreich *et al.* AJRI, 31: 69-76 (1994);

Clark *et al.* Human Reprod., 9: 2270-2277 (1994).

7. I am informed that there is a two-part test for determining whether a claim is obvious. This test requires considering whether the prior art (i) would have suggested to one of ordinary skill in the art that the claimed invention should be carried out and (ii) would have had a reasonable likelihood of success, viewed in the light of the prior art.

8. I understand that the Examiner states that Feinberg teaches a method of treating infertility by administering TGF $\beta$  along with antigens such as sperm into the reproductive tract of a prospective mother. Allegedly, the TGF $\beta$  can be administered before, simultaneously with, or after, paternal antigens. Feinberg states that the TGF $\beta$  aids implantation of a conceptus by stimulating the production of trophoblast fibronectin by the conceptus.

9. One of ordinary skill in the art would have known that TGF $\beta$  has an *in vivo* half-life of only a few minutes. Wakefield *et al.*, *J Clin Invest.* 86:1976-84 (1990)(appended to this

declaration as EXHIBIT 1); Philipa *et al.*, *J Biol Chem.* 266:22290-6 (1991)(EXHIBIT 2). In view of Feinberg's clearly stated objective of stimulating production of fibronectin by the conceptus, one of ordinary skill in the art would have understood that Feinberg could only have contemplated increasing the success rate of assisted reproduction if TGF $\beta$  is delivered precisely at the time during which the preimplantation embryo arrives in the uterine cavity, and not a week or months before attempted conception. This is logical since Feinberg's methods are aimed at increasing fibronectin production in the conceptus – it would be pointless to administer TGF $\beta$  until a conceptus is present and able to respond to the TGF $\beta$ . Delivery of TGF $\beta$  at any other time prior to introduction of the conceptus would have no effect because the TGF $\beta$  would be degraded before it could contact the conceptus and have any effect on fibronectin production. Although Feinberg states that TGF $\beta$  and semen can be introduced into the maternal reproductive tract prior to introduction of the ovum, one of ordinary skill in the art would recognize that the time period between introduction of the TGF $\beta$  and the ovum would have to be on the order of minutes if there was to be any possibility for the TGF $\beta$  to stimulate fibronectin production.

10. Claim 105 of the '327 application requires that TGF $\beta$  be delivered at least one week before attempted conception, that is, at least one week before a conceptus possibly could be present in the prospective mother's reproductive tract.

11. Feinberg would not have provided any motivation to deliver TGF $\beta$  at least one week before attempted conception. Rather, because Feinberg states that the intended target of the TGF $\beta$  is the conceptus, the earliest time one would deliver the TGF $\beta$  would be immediately prior to the time of implantation, which is 4 days after conception.

12. I disagree with the Examiner's statement that it would have been obvious to treat recurrent miscarriage by inducing immune tolerance to a paternal antigen in a prospective mother. The Examiner argues that Prakash, Thaler *et al.* and Thomas *et al.* teach exposing the maternal genital mucosal surface to semen and that Thomas *et al.* teaches that semen contains an immunosuppressive factor, such as TGF $\beta$ , that suppresses postcoital T-cell response. The Examiner also states that Lea *et al.* teaches that patients suffering from recurrent spontaneous abortion are deficient in uterine TGF $\beta$ 2-producing suppressor cells. Clark *et al.* is cited as teaching that TGF $\beta$  has immunosuppressive activity that leads to induction of tolerance *in vivo* during the first trimester of pregnancy in humans. Nocera *et al.* is cited as teaching that human

seminal plasma contains a TGF $\beta$  precursor and Thaler is cited as teaching that human seminal plasma contains factors that suppress the maternal immune response to paternal antigens and could prime mothers for improved implantation rates.

13. The experiments described by Lea *et al.* showed that TGF $\beta$ 2-related molecules are released by decidual lymphoid cells and that the supernatant from these cells is able to suppress the *in vitro* immune activity of normal human blood lymphocytes (Figure 1, page 56) and suppress the generation of cytotoxic T lymphocytes using a mixed lymphocyte culture-cytotoxic lymphocyte (MLC-CTL) assay (Figure 3, page 58). The assay used by Lea *et al.* did not and could not show antigen-specific immune tolerance. At best the assay shows a generalised immunosuppression effect. Lea does not make any reference to immune tolerance. As a result, nothing in Lea *et al.* teaches or suggests that the cell supernatant can induce immune tolerance.

14. Similarly, the assay described by Nocera *et al.* did not and could not show antigen-specific immune tolerance. At best the assay shows a generalised immunosuppression effect. Nocera does not make any reference to immune tolerance. As a result, nothing in Nocera *et al.* teaches or suggests that the cell supernatant can induce immune tolerance.

15. Clark *et al.* describes that the TGF $\beta$ 2-related molecule released from CD56+ cells obtained from decidua of human first trimester pregnancy can inhibit T lymphocyte generation *in vitro* (using the MLC-CTL assay). As with Lea *et al.* and Nocera *et al.*, the *in vitro* assay used by Clark *et al.* did not and could not show antigen-specific immune tolerance. At best the assay shows a generalised immunosuppression effect. Clark does not make any reference to immune tolerance. As a result, nothing in Clark *et al.* teaches or suggests that the cell supernatant can induce immune tolerance.

16. Thomas *et al.* states that seminal plasma has some undefined and unexplained immunosuppressive effect on the cellular immune reaction of the female to male antigens after mating. Thomas does not make any reference to immune tolerance. Nothing in Thomas *et al.* teaches or suggests that seminal plasma can induce immune tolerance.

17. Thaler *et al.* discusses the generalised immunosuppressive activities of seminal plasma. There is no suggestion of immune tolerance.

18. Prakash et al discusses the generalised immunosuppressive properties of semen. There is no suggestion of immune tolerance.

19. Generalized immunosuppression is the suppression of the immune system towards all antigens. This phenomenon is not antigen-specific. The induction of generalized immunosuppression is immediate, resulting in changes in the proliferative ability of lymphocytes that is detectable within hours. Generalized immunosuppression is also a temporary phenomenon because it is not memory related and can be reversed once the suppressive agent is removed. Generalized immunosuppression has potentially significant detrimental side effects because it can result in the immune system becoming non-functional, leaving the host vulnerable to infectious diseases and tumor proliferation.

20. By contrast, immune tolerance is not a suppression of the immune response towards all antigens (i.e. “generalized” immunosuppression), but is a conducive active immune response towards a specific antigen. Even when the immune system is tolerant to a particular antigen or antigens, it still is fully functional to other antigens and the host is not vulnerable to infectious diseases and tumour proliferation. Furthermore, the induction of immune tolerance requires a priming event, and involves a process of activation and expansion of immune mediating cells (T-lymphocytes) that proceeds over several days (generally at least 2-3 days after antigen administration, to allow for the necessary intermediate events of antigen processing and presentation, T-lymphocyte activation and proliferation) (Huang *et al*, *J. Immunol.*; 170:3945-3953 (2003)).

21. Generalized immune suppression is inconsistent with activation of immune tolerance since the priming, activation and expansion of the immune cells responsible for immune tolerance is inhibited by generalized immune suppression; induction of generalized immune suppression in a prospective mother would actually inhibit the induction of immune tolerance. Finally, immune tolerance is memory related and is long lasting, for at least as long as the activating antigen persists in the system, and immune tolerance established prior to conception lasts the entire period of pregnancy (Tafari *et al.*, *Science* 270:630-3 (1995)).

22. None of the assays described by Lea *et al.*, Nocera *et al.*, Clark *et al.*, Thomas *et al.*, Thaler *et al.*, or Prakash are capable of demonstrating any induction of immune tolerance. Moreover, none of the references, either alone or in combination, teach or suggest that TGF $\beta$  or semen, or the combination of TGF $\beta$  and semen, can induce tolerance in a prospective mother.

23. In summary, Feinberg states that TGF $\beta$  can increase the chance of successful implantation of a conceptus by stimulating fibronectin production in the conceptus. Feinberg does not mention immune tolerance, nor suggest that TGF $\beta$  might play a role in the induction of tolerance. The other references (Lea *et al.*, Nocera *et al.*, Clark *et al.*, Thomas *et al.*, Thaler *et al.*, and Prakash) suggest at most that TGF $\beta$  present in semen may have some ill-defined local generalized immunosuppressive effect in a prospective mother, but fail to teach or suggest that exogenous TGF $\beta$  can be used in combination with paternal antigens to induce tolerance in the mother.

24. Finally, the invention defined by the claims of the '327 application has received wide recognition by peers in the reproductive immunology field because it provides a solution to an unmet need. This peer recognition is evidenced by the award of the 2005 J. Christian Herr Award to Dr. Sarah A. Robertson. This award was presented on June 16, 2005, at the 25<sup>th</sup> Annual Meeting for the American Society for Reproductive Immunology in Providence, RI. I was present at this presentation. The Herr Award is given to an individual who has made outstanding achievements in reproductive immunology research. Dr. Robertson's research explores the roles of cytokines in early pregnancy and specifically identified TGF $\beta$  in seminal plasma as an agent capable of inducing immune tolerance in the female reproductive tract. This latter discovery described a new paradigm for the role of male factor signalling in the events of early pregnancy, and led directly to the methods for the treatment of reproductive disorders described in the '327 application.

25. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

3/13/06  
Date

Carolyn B. Coulam M.D.  
Carolyn B. Coulam, M.D.

## ***Curriculum Vitae***

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Carolyn Bedke Coulam, M.D., born April 14, 1943, in Salt Lake City, Utah, is the proud mother of 10 children age's 33-18 years. Dr. Coulam is recognized as a world leader in Reproductive Endocrinology, Reproductive Immunology, research and treatment of early pregnancy wastage.

**Name:** Carolyn Bedke Coulam, M.D.

**Birthday:** April 14, 1943

**Birthplace:** Salt Lake City, Utah

**Citizenship:** United States of America

**Social Security Number:** 220-38-3647

**Home Address:** 111 E. Chestnut Street  
Chicago, Illinois 60611

**Business Address:** 233 E. Erie Street  
Suite 500  
Chicago, Illinois 60611

**Business Phone:** (313) 944-2600

### **EDUCATION AND TRAINING**

<b>Undergraduate:</b>	1963	Bachelors of Science (BS)	University if Utah Salt lake City, Utah
<b>Graduate:</b>	1967	Master of Science (MS)	University of Utah Salt lake City, Utah
	1967	Medical Doctor (MD)	University of Utah Salt Lake City, Utah
<b>Postgraduate:</b>	1967-1968	Rotating Internship	Sven Gunderson, M.D. Mary Hitchcock Memorial Hospital Hanover, New Hampshire
	1968-1972	Residency	David Decker, M.D. Mayo Graduate Scholl of Medicine Obstetrics and Gynecology Rochester, Minnesota

## MEMBERSHIPS IN PROFESSIONAL / SCIENTIFIC SOCIETIES

1967	Alpha Epsilon Delta
1972	Minnesota Obstetrician and Gynecologist
1973	Sigma XI
1973	Forceps Society
1976	Central Association of Obstetricians and Gynecologist
1977	American Fertility Society
1979	American College of Surgeons
1979	Society for Gynecologic Investigation
1980	American Society for Immunology of Reproduction
1981	Transplantation Society
1982	American Society for Reproductive Transplant Physicians
1984	Society for Reproductive Endocrinologists
1985	Association of Professors of Gynecology and Obstetrics

## COMMITTEE APPOINTMENTS

Committee of Recruitment	1970-1971	American College of Obstetricians and Gynecologists
National Executive Committee	1970-1971	American College of Obstetricians and Gynecologists
Executive Committee, District VI	1970-1971	American College of Obstetricians and Gynecologists
Program Committee	1972-1973	Minnesota Obstetrical and Gynecological Society
Advisory Committee	1973-1976	Mayo Medical School of Medicine
Research Committee	1972-1976	Mayo Clinic, Depart. Of Obstetrics and Gynecology
Research Committee	1972-1985	Mayo Clinic, Depart. Of Obstetrics and Gynecology
Curriculum Committee	1972-1985	Mayo Medical School of Medicine
Thesis Committee	1972-1985	Mayo Medical School of Medicine
Institutional Review Board	1996-1999	Center for Human Reproduction

## APPOINTMENTS AND POSTIONS

Associate Consultant	01/72-07/72	Department of Obstetrics and Gynecology Mayo Clinic, Rochester, MN
Consultant	07/72-08/85	Department of Obstetrics and Gynecology Mayo Clinic, Rochester, MN
Instructor	11/72-07/85	Department of Obstetrics and Gynecology Mayo Medical School, Rochester, MN
Assistant Professor	07/75-07/81	Department of Obstetrics and Gynecology Mayo Medical School, Rochester, MN



## **APPOINTMENTS AND POSTIONS (continued)**

Associate Professor	07/81-1984	Department of Obstetrics and Gynecology Mayo Medical School, Rochester, MN
Professor	1984-08/85	Department of Obstetrics and Gynecology Mayo Medical School, Rochester, MN
Medical Director	08/86-09/91	Methodist Center for Reproductive and Transplantation Immunology Methodist Hospital of Indiana, Inc. Indianapolis, IN
Director	09/91-03/96	Division of Reproductive Immunology Genetics and IVF Institute Fairfax, VA
Staff Member	09/94-03/96	Department of Obstetrics and Gynecology Fairfax Hospital Falls Church, VA
National Director	1996-1999	Division of Reproductive Immunology Center for Human Reproduction Chicago, IL
Medical Director	2000-2005	Sher Institute for Reproductive Medicine/RPL Chicago, IL
Director	2000-present	Millenova Immunology Laboratories Chicago, IL

## **CERTIFICATION AND LICENSURE**

Specialty Certification	November, 1974	Board Certified in Obstetrics and Gynecology	
	February, 1979	Board Certified in Reproductive Endocrinology	
Medical Licensure	1968	Minnesota	018344
	1972	California	G-023712
	1985	Pennsylvania	MD-034539-E
	1986	Indiana	0103418
	1991	Virginia	0101473687
	1996	Illinois	036-092625
	1998	New York	206821-1
	2004	Idaho	8978
	2004	Missouri	2004003726

**Committee Membership:**

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Gynecologic Practice Committee	1975-1985	American College of Obstetricians And Gynecologists
Committee on Sterilization of Mentally Retarded Minors	1975-1985	Mayo Clinic
Committee on Comprehensive Epilepsy	1975-1985	Mayo Graduate Scholl of Medicine
Graduate Medical Education Committee	1975-1977	Mayo Foundation
Continuing Medical Education Committee	1977-1979	Mayo Graduate School of Medicine
Medical Care Evaluation	1975-1977	Mayo Graduate School of Medicine
Revisions Committee	1975-1977	Central Association of Obstetrician and Gynecologists
Continuing Medical Education Committee	1979-1981	Mayo Alumni Association
Executive Committee	1981-1985	Mayo Alumni Association
Committee of Young Surgeons	1981	American College of Surgeon
Committee on Young Women Physicians	1981-Present	American Fertility Society
Program Directors Committee	1981-Present	Reproductive Endocrinology Training Programs
Health Care Commission	1981-1983	American College of Obstetricians and Gynecologists
Development Committee	1984-1985	American Fertility Society
Health Care Committee	1981-1983	American College of Obstetricians and Gynecologists
Patient Care and Standards Committee	1983-1985	The American Society of Transplant Physicians
Women's Council Member	1984-1985	American Fertility Society
Advisory Council, District VI	1984-1985	The American College of Obstetricians and Gynecologists
Executive Electoral Committee	1984-1985	Sigma XI
Council	1984-1985	American Society for Immunology Of Reproduction
Forum Committee	1984	Fundamental Surgical Problems

**Committee Memberships: (continue)**

Fertility and Maternal Health Drugs Advisory Committee	07/01/84-06/30/88	Food and Drug Administration
Council	1984-1985	The American College of Surgeons, Minnesota Chapter
Minnesota Credentials Committee	1985	The American College of Surgeons
Council	1985	Association of Professors of Gynecology and Obstetrics
Council	1985-Present	CITROG
Council Member	1985	Council on Resident Education in Obstetrics and Gynecology
Committee Member	1989-Present	Planned Parenthood Federation of America, Inc.
Editorial Board Members	1989-Present	American Journal of Reproductive Immunology

**Offices:**

Chairman, Junior Fellows, District VI	1970-1971	American College of Obstetricians and Gynecologists
Board of Governors	1977-1980	University Club
Councilor of Voting Staff	1980-1982	Mayo Clinic
Board Examiner	1981-1988	American College of Obstetricians and Gynecologists
Secretary-Treasurer	1982-1984	Minnesota Obstetrical and Gynecological Society
President-Elect	1985	Minnesota Obstetrical and Gynecological Society
Board of Governors	1982-Present	Minnesota Obstetrical and Gynecological Society
Vice-Chairperson	1983-1986	American College of Obstetricians And Gynecologists, Minnesota Chapter
Chairman	1981	Committee on Sterilization for the Mentally Retarded, Mayo Clinic
Chairman	1985-1988	Fertility and Maternal Health Drugs Advisory Committee of the Food and Drug Administration

**Offices: (continued)**

President	1987-1988	American Society for Immunology Of Reproduction
Council Member	07/01/89-06/30-93	Population Research council, National Institute of Child Health and Human Development
Chairman		Ethics Committee, American Society of Reproductive Immunology

**Editorial Boards:**

Mayo Clinic Health Letter	1982-1984	
Obstetrics and Gynecology	1984-1985	
Trophoblast Research	1985-Present	
American Journal for Immunology of Reproduction and Microbiology	1988-Present	
Adolescent and Pediatric Gynecology	1989-Present	
Ad Hoc Reviewer for:	Mayo Clinic Proceedings American Journal of Obstetrics and Gynecology Human Reproduction Journal of Endocrinology and Metabolism New England Journal of Medicine	

**HONORS AND AWARDS**

1965, 1966, 1967	Mosby Book Award University of Utah
1967	Busch Research Award University of Utah
1971	Randall Travel Award Mayo Graduate School of Medicine
1979	Certificate of Merit Award

**Central Association of Obstetrics and Gynecology:**

1980	First Prize Award Central Association of Obstetrics and Gynecology
1981	First Prize Award for Scientific Paper American College of Obstetrics and Gynecology
1987	Certificate of Merit Award Central Association of Obstetrics and Gynecology
1989	General Program Prize Award American Fertility Society

**Teachings and Thesis Committees:**

---

Polly Marchbanks, Ph.D.	June, 1985	
Debbie del Junco, Ph.D.	June, 1987	University of Texas Houston, Texas
Terri Woessman, Ph.D.	June, 1987	Mayo Graduate School of Medicine Rochester, Minnesota
Lecturer	1972-1985	Human Growth and Development Mayo Medical School Rochester, Minnesota
Lecturer	1972-1985	Embryology Mayo Medical School Rochester, Minnesota
Lecturer	1972-1985	Obstetrics and Gynecology Mayo Medical School Rochester, Minnesota
Lecturer	1978-1985	Pharmacology Mayo Medical School Rochester, Minnesota
Preceptor	1972	Obstetrics and Gynecology Mayo Medical School Rochester, Minnesota
Course Curriculum Committee	1980-1985	Mayo Medical School Rochester, Minnesota
First Year Curriculum Committee	1980-1985	Endocrinology Mayo Medical School Rochester, Minnesota
Fourth Year Curriculum Committee	1979-1985	Mayo Medical School Rochester, Minnesota
Director, Reproductive Endocrinology	1981-1985	Mayo Medical School Rochester, Minnesota
Endocrinology Training Program	1985-1986	University of Pittsburgh
Director, Reproductive Endocrinology		Center for Reproduction and Transplantation Methodist Hospital Graduate School of Medicine
Director, Core Curriculum or Reproductive Biology		Center for Reproduction and Transplantation Methodist Hospital Graduate School of Medicine

**Research:**

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PMS: New Treatment and Trials	1984-1985	Mayo Clinic
LA and Reproductive Performance	1983-1985	Upjohn
nRH Analogy in the Treatment of Endometriosis	1984-1985	Syntex
Osteoporosis Prevention with Estraderm Patches	1984-1986	Cieba-Geigy
Prevention of Primary Habitual Abortion	1985-1986	Magee-Woman's Hospital
Prevention of Repeated Pregnancy Loss in Secondary Aborting Women	1985-1986	Magee-Woman's Hospital
Plasma MBP Levels During Late Pregnancy	1985-1989	NIH Grant #09728
Plasma MBP Levels During Late Pregnancy	1985-1992	NIH Grant #09728
CBP in Cells of Placental Bed	1985-1992	NIH Grant #09728
Immunogenetic Studies in IUGR	1985-1986	Department of Pathology University of Pittsburgh Magee-Woman's Hospital
Luteal Phase Defect	1986-1992	Methodist Hospital
Normal Reproducing Couples	1986-1992	Methodist Hospital
Prevention of Pregnancy Losses in Recurrent Spontaneous Aborters	1986-1990	Methodist Hospital
Oral Contraceptive	1988-1991	Wyeth-Ayerst
Trancervical Balloon Tuboplasty	1988-1990	Bard, Inc.
Premarin / Medroxyprogesterone	1989-1991	Wyeth-Ayerst
Intravenous Immunoglobulin	1989-1994	Sandoz
Clinical Trail to Evaluate the Efficacy of Frozen-Thawed Human Sperm in AIDS	1989-1993	NIH Grant #
Prevention of Repeated Pregnancy Loss On Secondary Aborting Women	1989-1993	Methodist Hospital
MK-906 Semen Production	1990-1992	Merck Laboratories

## CLINICAL RESPONSIBILITIES

### **Organized and Established:**

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Reproductive Endocrinology and Infertility Clinics  
Premenstrual Tension Syndrome Clinic  
Artificial Insemination Program  
In Vito Fertilization Program

### **Director of:**

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Program for In vitro Fertilization  
Reproductive Endocrinology Training Program  
Reproductive Immunology Training Program

## PUBLICATIONS

1. Richter GO, Pratt JH, Nichols DR, Coulam CB. Actinomycosis of the female genital organs. *Minn Med.* 1972 Nov;55(11):1003-60. Lee CY, Coulam CB, Jiang NS, Ryan RJ. Receptors for human luteinizing hormone in human corpora luteal tissue. *J Clin Endocrinol Metab.* 1973 Jan;36(1):148-52.
2. Coulam CB, Pratt JH. Vaginal hysterectomy: is previous pelvic operation a contraindication? *Am J Obstet Gynecol.* 1973 May 15;116(2):252-60.
3. Coulam CB, Nichols VR, Pratt JH. Use of fascia lata in gynecologic surgery. *Conn Med,* 1973 Nov;37(11):555-9.
4. Coulam CB. The hirsute person: a commentary. *Med Clin North Am.* 1974 Jul;58(4):877-84. No abstract available.
5. Coulam CB, Hammond CB. Letter: CB-154. *Fertil Steril.* 1976 Mar;27(3):345-6. No abstract available.
6. Bartizal FJ, Coulam CB, Gaffey TA, Ryan RJ, Riggs BL. Impaired binding of estradiol to vaginal mucosal cells in post-menopausal osteoporosis. *Calcif Tissue Res.* 1976 Aug;21 Suppl:412-6. No abstract available.
7. Tashjian JH, Coulam CB, Washington JA 2d. Vaginal flora in asymptomatic women. *Mayo Clin Proc.* 1976 Sep;51(9):557-61.
8. Annegers JF, Coulam CB, Abboud CF, Laws ER Jr, Kurland LT. Pituitary adenoma in Olmsted County, Minnesota, 1935-1977. A report of an increasing incidence of diagnosis in women of childbearing age. *Mayo Clin Proc.* 1978 Oct;53(10):641-3.
9. Bolton RA, Coulam CB, Ryan RJ. Search for antibodies to LH receptors in serum of women with polycystic ovarian disease. *Surg Forum.* 1979;30:464-6.
10. Coulam CB, Annegers JF, Abboud CF, Laws ER Jr, Kurland LT. Pituitary adenoma and oral contraceptives: a case-control study. *Fertil Steril.* 1979 Jan; 31(1):25-8.
11. Coulam CB. Testicular regression syndrome. *Obstet Gynecol.* 1979 Jan;53(1):44-9.
12. Coulam CB, Lackore RC. Pregnancy associated with the empty sella syndrome and hyperprolactinemia. *Fertil Steril.* 1979 Feb;31(2):220-3.
13. Coulam CB, Ryan RJ. Premature menopause. I. Etiology. *Am J Obstet Gynecol.* 1979 Mar 15;133(6):639-43.
14. Austin GE, Coulam CB, Ryan RJ. A search for antibodies to luteinizing hormone receptors in premature ovarian failure. *Mayo Clin Pro.* 1979 Jun;54(6):394-400.
15. Coulam CB, Annegers JF. Do anticonvulsants reduce the efficacy of oral contraceptives? *Epilepsia.* 1979 Oct;20(5):519-25.
16. Davidson BJ, Riggs BL, Coulam CB, Toft DO. Concentration of cytosolic estrogen receptors in patients with postmenopausal osteoporosis. *Am J Obstet Gynecol.* 1980 Feb 15;136(4):430-3.
17. Waltzer WC, Coulam CB, Zincke H, Sterioff S, Frohnert PP. Pregnancy in renal transplantation. *Transplant Proc.* 1980 Mar;12(1):221-6.
18. Bammann BL, Coulam CB, Jiang NS. Total and free testosterone during pregnancy. *Am J Obstet Gynecol.* 1980 Jun 1;137(3):293-8.



19. Bolton RA, Coulam CB, Ryan RJ. Specific binding of human chorionic gonadotropin to human corpora lutea in the menstrual cycle. *Obstet Gynecol.* 1980 Sep;56(3):336-8.
20. Bolton RA, Coulam CB, Ryan RJ. Anovulation with estrogen production: receptor disorders? *Obstet Gynecol.* 1980 Sep; 56(3):344-8.
21. Ory SJ, Coulam CB, Zincke H. Estrogen secretion in a renal allograft population. *Int J Fertil.* 1981;26(1):40-4.
22. McCormick PD, Razel AJ, Spelsberg TC, Coulam CB. Absence of high-affinity binding of progesterone (R 5020) in human placenta and fetal membranes. *Placenta Suppl.* 1981;3:123-32.
23. Coulam CB. Hormonal status of galactosaemia homozygotes. *Lancet.* 1981 Jan 17;1(8212):165.
24. Coulam CB, Lufkin EG. Absence of adrenal failure in the polyglandular failure syndrome with primary ovarian failure. *Fertil Steril.* 1981 Mar;35(3):365-6. No abstract available.
25. Coulam CB. Age, Estrogens, and the psyche. *Clin Obstet Gynecol.* 1981 Mar;24(1):219-83. Review.
26. McCormick PD, Razel AJ, Spelsberg TC, Coulam CB. Evidence for an androgen receptor in the human placenta. *Am J Obstet Gynecol.* 1981 May 1;140(1):813.
27. James AE Jr, Coulam CB, Rao GU, Hall DL. Newer diagnostic medical imaging techniques: their implications as evidence. *J Leg Med,* 1981 Jun;2(2):151-67.
28. Coulam CB, Laws ER Jr, Abboud CF, Randall RV. Primary amenorrhea and pituitary adenomas. *Fertil Steril.* 1981 Jun;35(6):615-9.
29. Coulam CB, Kempers RD, Randall RV. Premature ovarian failure: evidence for the autoimmune mechanism. *Fertil Steril.* 1981 Aug;36(2):238-40. Abstract available.
30. Coulam CB. Hyperglycinemia and pregnancy. *Clin Genet.* 1981 Sep;20(3):238-9.
31. Coulam CB, Field CS, Kempers RD. Spontaneous bilateral ovarian hemorrhages as a cause of premature ovarian failure. *Mayo Clin Proc.* 1981 Dec; 56(12):762-4. No abstract available.
32. Coulam CBM, Julian CG, Fleisher AC. Clinical efficacy of CT and US in evaluating gynecologic tumors. *Appl Radiol.* 1982 Jan-Feb;11(1):79-82, 84-8.
33. Coulam CB, Zincke H, Sterioff S. Relationship between donor age and outcome of pregnancy in a renal allograft population. *Transplantation.* 1982 Jan;33(1):97-9. No Abstract available.
34. Stretchy JH, Coulam CB, Spelsberg TC. Comparison of estrogen receptors in human premenopausal and postmenopausal uteri: indication of biologically inactive receptor in postmenopausal uteri. *Am J Obstet Gynecol.* 1982 Feb 15;142(4):372-82.
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